



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,724	02/06/2001	Steven M. Ruben	PZ011	2764

22195 7590 05/15/2003

HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE, MD 20850

EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/15/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/776,724

Applicant(s)

RUBEN ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on March 03, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicants' arguments in Paper No. 14, filed March 03, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. It is acknowledged that Applicants have cancelled claims 1, 13, 16-20, and 22; and amended claims 29, 30, 34, 35, 39, 40, 49, and 50.
3. Claims 24-53 are examined on the merits.

### LACK OF UTILITY UNDER 35 U.S.C. § 101

4. Claims 24-53 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or in the alternative, a well-established utility. This rejection is maintained with respect to claims 24-53, as recited in the previous office action Paper No. 13, mailed December 03, 2002.
5. Applicants argue that the "Examiner has not met the burden that is necessary to establish and maintain a rejection of claims 24-53" (Pages 3-4) which are directed to SEQ ID NO: 142; the said arguments have been found to be unpersuasive. It is acknowledged that the burden is on the Examiner to establish a *prima facie* case and provide evidentiary support for a lack of utility rejection under 35 U.S.C. § 101. The burden has been met in the prior office action, Paper 13, mailed December 03, 2002. Applicants are directed to paragraph 9, pages 4-5, of the said prior office action. The discussion relating to establishing a *prima facie* case

Art Unit: 1631

and providing evidentiary support (Molecular Biology of the Cell, Page 4, Lines 2-17) clearly support that this instant application lacks specific and substantial support for the claimed subject matter. Therefore, the lack of utility rejection under 35 U.S.C. § 101 is maintained.

6. Further, Applicants argue that the Examiner has not explicitly discussed nor provided evidence that the asserted utilities are not credible (Paper No. 14, page 4, ¶ 4). It is noted that the Examiner is following the general principles governing utility rejection as cited in the MPEP § 2107.01. The instant application is examined in regard to the said application meeting the specific, substantial, and credible utility, or in the alternative well-established utility requirements as further defined on page 3, paragraph 6, Paper 13, mailed December 03, 2002. The instant application must provide adequate support for either all the combination of specific, substantial, and credible utility, or a well established utility, however, lacking support for either a well established utility or one of the listed combination of requirements is sufficient grounds for the lack of utility rejection under 35 U.S.C. § 101. It is reiterated that claims 24-53 are rejected under 35 U.S.C. § 101 for lacking specific and substantial utility for the claimed subject matter.

7. Specific to the Applicants' argument and pointed to support for specific and substantial asserted utility, it is acknowledged that Applicants disclose, "the gene is expressed primarily in osteoclastoma." However, there is not any specific or substantial disclosure that supports the said argument. The disclosure directed to SEQ ID NO: 142 and the corresponding protein does not provide sufficient support that the claimed subject matter has specific or substantial asserted utilities.

Art Unit: 1631

8. Further, Applicants' argument that "the claimed polypeptide is overexpressed in osteoclastoma tissue as opposed to normal bone tissue" is acknowledged. However, Applicants disclose that "expression of this gene at significantly higher or lower levels may be routinely detected in certain or cell types" (page 121, lines 26-29). Applicants' argument is not consistent with the disclosure in this instant specification with regard to the level of expression of the said gene. It is not specific if the claimed asserted utilities are due to the gene expressing at a significantly higher or lower level. The specification does not provide substantial support that the asserted utilities are directed to the change in the expression level of SEQ ID NO. 142. Therefore, the disclosure as directed to SEQ ID NO. 142 in this instant application would require one skilled in art to carry further research to identify or reasonably confirm a "real world" context for the use of the claimed invention.

9. It is suggested that a declaration under 37 CFR 1.132 containing data directed to the specific and substantial asserted utilities of the claimed subjected as directed to SEQ ID NO. 142 could be used to overcome the lack of utility rejection under 35 U.S.C. § 101.

#### **LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

10. Claims 24-53 are also rejected under 35 U.S.C. § 112, first paragraph. This rejection is maintained with respect to claims 24-53, as recited in the previous office action Paper No. 13, mailed December 03, 2002.

11. Applicants argue that the lack of utility rejection in Paper 13, mailed December 03, 2002, was improper, therefore, the said lack of utility rejection did not provide basis for the 35 U.S.C. § 112, first paragraph, Paper No. 14, filed March 03, 2003.

Art Unit: 1631

12. For the reasons discussed above in regard to the lack of utility rejection, Applicants' arguments have been acknowledged and found to be unpersuasive.

**NEW MATTER UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

13. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended subject matter in these claims is considered to be new matter because they are not disclosed in the original specification. This is a NEW MATTER rejection.

14. This rejection is maintained with respect to claim 25, as recited in the previous office action Paper No. 13, mailed December 03, 2002.

15. Applicant's argument that the instant specification provides written description basis for sub-segments of SEQ NO: 142 has been found to be unpersuasive. It is acknowledged that the claimed subject matter directed to the polypeptide (amino acid residues 1-54) of SEQ NO: 142 has written description basis as originally filed. However, the instant specification does not provide support for Applicant's argument, which is directed to generic expression and processing of sub-segments of the polypeptide SEQ NO: 142. Therefore, the said new matter rejection is maintained to claim 25 because the instant specification lacks written description basis as originally filed for specific sub-segments of SEQ ID NO:142.

Art Unit: 1631

16. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

17. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **CONCLUSION**

18. NO CLAIM IS ALLOWED.

19. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

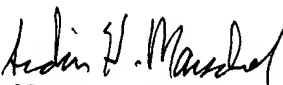
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Art Unit: 1631

22. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
5/13/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER